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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,781	09/24/2003	Juha Apajalahti	79428	6390

22242 7590 02/23/2006

FITCH EVEN TABIN AND FLANNERY
120 SOUTH LA SALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,781	APAJALAHTI ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/251,503.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-14 are pending and under consideration in this Office Action.

2. The terminal disclaimer filed on 12/07/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,638,746 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The rejection of claims 1-11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,638,746 stated in the previous Office Action dated 09/12/2005 has been withdrawn in view of the accepted terminal disclaimer filed on 12/07/2005.

3. The objection to the disclosure stated in the previous Office Action dated 09/12/2005 has been withdrawn. Applicants have submitted an amendment to the specification filed on 12/05/2005 which states that the application is a continuation of Serial No. 10/251,503 (US Patent 6,638,746, which is a continuation of Serial No. 09/242,499 (abandoned), which is the US National Stage filing of PCT Application No. PCT/EP97/04385, and claims foreign priority under 35 U.S.C. 119(a)-(d) to foreign patent application 9616957.8 filed in the United Kingdom on 08/13/1996.

4. The rejection of claims 6-8 under 35 USC 101 as being directed to non-statutory subject matter and the corresponding rejection under 35 U.S.C. 112, first paragraph, as stated in the previous Office Action dated 09/12/2005 has been withdrawn in view of applicants' amendment to these claims filed on 12/05/2005, where the claims have been amended to recite the phrase "an isolated".

5. The rejection of claims 1-11 under 35 U.S.C. 112, second paragraph, as being indefinite as stated in the previous Office Action dated 09/12/2005 has been withdrawn in view of applicants' amendment to these claims filed on 12/05/2005, where the previously recited PCR amplification conditions have been deleted.

NUCLEOTIDE AND/OR AMINO ACID SEQUENCE DISCLOSURES

6. This application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825

for the reason(s) set forth: Table 5 and page 25 of the specification lists several nucleotide sequences without a SEQ ID NO identifier for each nucleotide sequence. Applicants are requested to correct the specification to place the application in compliance with the sequence rules of 37 CFR §§ 1.821 through 1.825.

Furthermore, the examiner requests that other nucleotide or amino acid sequences disclosed in the application be corrected to include a specific SEQ ID NO identifier, if necessary, according to the sequence rules of 37 CFR §§ 1.821 through 1.825.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 10, 13, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

In claim 10, line 5, the phrase "or functional equivalents thereof" renders the claim vague and indefinite. The specific "functional equivalents" are not known and not recited in the claim. Thus, the metes and bounds of the claim are uncertain because it is not clear what applicants are referring to.

Furthermore, claim 10 recites the phrase "SEQ ID NO: 1 or a fragment thereof" which is vague and indefinite. The specific nucleotide sequence of the "fragment" of SEQ ID NO: 1 which can be used as a DNA probe is not known and not recited in the claim.

Claim 13 is vague and indefinite for reciting the phrase "two or more oligonucleotide primers which hybridize to SEQ ID NO: 1". The metes and bounds of the claim are not certain because the specific nucleotide sequences of the "two or more oligonucleotide primers" which will specifically hybridize to SEQ ID NO: 1 are not known and not recited in the claim. Claim 14 which depends from claim 13 is also rejected because it does not correct the defect of claim 13.

Furthermore, claim 13 is indefinite for reciting the phrase "a complement of SEQ ID NO: 1". The claim as written encompasses any complement of any part of the nucleotide sequence of SEQ ID NO: 1. It is not clear if applicants intended to recite the phrase "the full complement of SEQ ID NO: 1".

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid of SEQ ID NO: 1, an isolated host cell transformed with a nucleic acid of SEQ ID NO: 1, and a method for identifying a nucleic acid molecule which encodes a phytase using SEQ ID NO: 1, and a method for the production of the nucleic acid sequence of SEQ ID NO: 1 using the specific PCR primers listed on page 25 of the specification; does not reasonably provide enablement for any nucleic acid that hybridizes to SEQ ID NO: 1 under the recited hybridization conditions of 6xSSC, 0.6% SDS, 50°C and any method for the production of any nucleic acid which encodes a phytase using any two or more PCR primers which hybridize to SEQ ID NO: 1 or to any complement of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

Applicants' arguments filed 12/07/2005 have been fully considered but are not persuasive. Applicants' position is that the amount of experimentation to identify specific nucleic acid sequences that hybridize under the recited conditions to SEQ ID NO: 1 is very routine for one of ordinary skill in the art. Applicants argue that one of skill could easily carry out a Southern blot hybridization experiment to identify an isolated nucleic acid encoding the claimed phytase using the recited hybridization conditions. The examiner respectfully disagrees for the reasons of record as supplemented below.

The nature and breadth of claims 1-12 encompass any nucleic acid that hybridizes to SEQ ID NO: 1 under the recited hybridization conditions of 6XSSC, 0.6% SDS, and 50°C. While the specification provides guidance for SEQ ID NO: 1, the specification does not provide guidance,

prediction, and working examples for searching and screening for the claimed nucleic acid encoding the claimed phytase under the recited hybridization conditions of 6XSSC, 0.6% SDS, and 50°C, which are deemed to be a low stringency hybridization condition because of the recited high salt concentration in the 6X SSC buffer and recited low temperature of 50°C. Because of this low stringency hybridization conditions, a very large number of nucleic acids must be searched and screened to identify the claimed nucleic acid encoding the claimed phytase.

Thus, an undue amount of trial and error experimentation must be preformed. Such experimentation entails hybridizing any nucleic acid to SEQ ID NO: 1 under the recited low stringency conditions of 6XSSC, 0.6% SDS, and 50°C. Then each and every nucleic acid that hybridizes to SEQ ID NO: 1 must be expressed in a host cell to determine whether it is able to encode the functional phytase as claimed. Such trial and error searching and screening is outside the realm of routine experimentation. General teachings from the specification using enzyme assays are not guidance for making the invention.

In view of the above considerations, the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make any nucleic acid that hybridizes to SEQ ID NO: 1 under the recited low stringency conditions of 6XSSC, 0.6% SDS, and 50°C.

The nature and breadth of the claims 13 and 14 encompass any method for the production of any nucleic acid which encodes a phytase using any two or more PCR primers which hybridize to SEQ ID NO: 1 or to any complement of SEQ ID NO: 1. While the specification provides guidance for SEQ ID NO: 1 and the 5' and 3' PCR primers listed on page 25 of the specification for PCR amplifying SEQ ID NO: 1, the specification does not provide guidance, prediction, and working examples for making and using any two or more PCR primers of any nucleotide sequence and structure which can specifically PCR amplify SEQ ID NO: 1. Thus, an undue amount of trial and error experimentation must be preformed to determine these specific PCR primers which will specifically PCR amplify SEQ ID NO: 1.

Such experimentation entails searching and screening for every PCR primer of any nucleotide sequence that will specifically hybridize to SEQ ID NO: 1 and PCR amplify only SEQ ID NO: 1. Such trial and error searching and screening is outside the realm of routine experimentation. The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific SEQ ID NO of the PCR primers which will specifically PCR amplify SEQ ID NO: 1. Without such guidance, the amount of experimentation left to those skilled in the art to make the invention is undue.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

TEKCHAND SAIDHA
PRIMARY EXAMINER